

K061133

JUL 11 2006

510(k) Summary of Safety and Effectiveness

Safe Medical Devices Act of 1990 (SMDA)

510(k) Summary

Name of Firm:	NovaSpine LLC 15 Heritage Court Tarrytown, NY 10591 Telephone: 914-909-6577 Fax: 914-909-6577
510(k) Contact:	Mr. Hamid Khosrowshahi NovaSpine LLC PO Box 969 Elmsford, NY 10523
Manufacture:	SIMEX Medizintechnik, GmbH Mozartstrasse 13 78652 Deisslingen, Germany
Trade Name:	SIMEX Suction Pumps Models: SIMEX "AC20", SIMEX "AC20K", SIMEX "AC30", SIMEX "DC20", SIMEX "DC30" and SIMEX "DC30S"
Common Name:	Suction / Aspiration Pump
Classification:	Suction / Aspiration Pump FDA 21 CFR 878.4780 Powered Suction Pump Class II
Device Product Code	BTA - Pump, Portable, Aspiration, (Manual or Powered)
Substantial Equivalency	Code: BTA Precision Medical, Inc. "Easy Go", K 971749 Medela, Inc. "Vario", K 983552

Device Description:

The SIMEX Suction Pump is a lightweight portable or stationary suction/aspirator pump for medical suction procedures where secretions, blood and other body fluids must be removed through the application of continuous negative pressure. Applications range from hospital, medical practice, emergency care, ambulance, and in home usage.

The SIMEX Suction Pumps have two Models. These Models have the same physically size and function but are differentiated in capacity as summarized below:

Table 1

<p>1. The SIMEX AC Model powered with alternating power. This Model has of three versions:</p> <p>a. SIMEX "AC20",</p> <ul style="list-style-type: none">i. Suction 18 l/min,ii. Noise 56 db (A),iii. Weight 3200 g,iv. Operation Continuousv. Color: Blue <p>b. SIMEX "AC20K"</p> <ul style="list-style-type: none">i. Suction 18 l/min,ii. Noise 63 db (A),iii. Weight 3200 g,iv. Operation 20 Minv. Color: Blue <p>c. SIMEX "AC30"</p> <ul style="list-style-type: none">i. Suction 28 l/min,ii. Noise 61 db (A),iii. Weight 3900 g,iv. Operation 30 Minv. Color: Green	<p>2. The SIMEX DC Model using an on board battery. This Model has of three versions:</p> <p>a. SIMEX "DC20",</p> <ul style="list-style-type: none">i. Suction 20 l/min,ii. Noise 63 db (A),iii. Weight 3100 g,iv. Operation 20 Minv. Color: Red <p>b. SIMEX "DC30",</p> <ul style="list-style-type: none">i. Suction 28 l/min,ii. Noise 63 db (A),iii. Weight 3500 g,iv. Operation 20 Minv. Color: Yellow <p>c. SIMEX "DC30S"</p> <ul style="list-style-type: none">i. Suction 28 l/min,ii. Noise 62 db (A),iii. Weight 3500 g,iv. Operation 45 Minv. Color: Yellow
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Models designed for mounting on a panel and packaged with a special "wall holder" are so designated with the letter "W" after the model and version number, e.g., "SIMEX DC 20W". All moving and electrical components are housed in a moulded compact plastic housing (130 mmx359 mmx290 mm). The unit includes attachment for an external power supply and/or a battery charger.

The vacuum is produced with a maintenance-free electrical piston or diaphragm vacuum pump. The vacuum pump transmits negative pressure throughout the tubing-system and the collection jar to a suction catheter that aspirates secretions or liquid from the body. The aspirated fluids are collected in the collection jar that is isolated from the pump by a hydrophobic filter. It also has a mechanical overflow protection in the lid of the collection jar to further prevent the fluids from being sucked into the pump. The filters are single use attachments that can be readily exchanged. The tubing and collection jar can either be replaced after use or sterilized using chemical disinfectants or can be autoclaved in accordance with the instructions supplied. Alternatively the collection jar can be replaced with a holder and a disposable aspiration bag.

A secondary air valve placed in the suction system can regulate the degree of vacuum and flow rate. The actual suction capacity can be estimated from the analogue manometer mounted on the pump. The pump vacuum can be manually adjusted using the regulating valve and the vacuum gage. The device can be adjusted to low vacuum values for use in nasal, pharyngeal and tracheal areas. Note that all controls are manual and the pump does not require any electronic process control.

The pump can be easily moved by hand or (versions that have a "W" designation) rapidly mounted to vehicle sides, room walls or wheel chairs. The SIMEX DC models have integrated electric supply enables charging and operation of the pump with the 12 to 24 Volts DC power supply. Also, if the units are used in home care, hospitals or clinical practices the SIMEX AC or DC models can be directly connected to AC power supplies for operation.

Since neither the pump nor its components come in direct contact with the patient sterilization is not required. The SIMEX Suction Pump is composed of two parts:

1. The pump, power unit and power supply all housed in a single unit
2. The consumable components such as:
 - Collection jar (secretion container),
 - Related hoses (tubing)
 - Hose connectors

The operating details of both models, SIMEX AC and SIMEX DC, are given in the operating manuals for the pumps (Product Inserts). These include detail list of all accessories that can be used with each suction pump, the part numbers, and the specifications for their use.

Details regarding the assembly and disassembly of each model are given in Service Instructions. These Service Instruction are for use by trained technicians who are familiar with the product. They are not to be used by untrained end users. These instructions will not be packaged with the pump.

Manufacturing:

The SIMEX suction pumps are manufactured in accordance with EEC Directive 93/42/EEC Annex IX and classified as suction unit of Class IIa. They all bear the "CE" marking for CE 0483 and meet the interference requirements for IEC 601-1-2/EN 60601-1-2. All SIMEX pumps are manufactured under recognized medical technical regulations and directions of the laws relating to medical products. The quality management is in accordance with certified international standards.

Performance Data:

SIMEX Suction Pumps are classified under FDA 21 CFR 878.4780 "Powered Suction Pump" Class II. A summary performance data is provided in Table 1 above "Device Description".

Basis For Substantial Equivalence:

This product is substantially equivalent to similar devices with similar technical specifications currently on the market such as:
Precision Medical, Inc. "Easy Go", K 971749 and Medela, Inc. "Vario", K 983552.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 11 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NovaSpine LLC
% Mr. Hamid Khosrowshahi
President
P.O. Box 969
Elmsford, NY 10523

Re: K061133

Trade/Device Name: SIMEX Suction Pump models: SIMEX AC20 pn 10401, SIMEX 20K pn 10400, SIOMEX AC30 pn 10501, SIMEX DC20 pn 10601, SIMEX DC30 pn 10701, SIMEX DC30S pn 10703

Regulation Number: 21 CFR 878.4780

Regulation Name: Powered suction pump

Regulatory Class: II

Product Code: BTA

Dated: April 20, 2006

Received: April 24, 2006

Dear Mr. Khosrowshahi

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

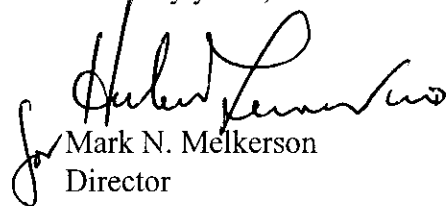
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K061133

Device Name:

SIMEX Suction Pump models:

AC Power

DC Power

SIMEX AC20 pn 10401

SIMEX AC20K pn 10400

SIMEX AC30 pn 10501

SIMEX DC20 pn 10601

SIMEX DC30 pn 10701

SIMEX DC30S pn 10703

Indication for Use:

The SIMEX Portable Suction/Aspirator/Vacuum system is indicated and used for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from wounds or from patient's airway or respiratory system, either during surgery or at patient's bedside.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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